REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. DISPOSITION OF CLAIMS

Claims 1, 14-23, and 26-36 are pending in the application. Claims 15-16, 23, and 26-32 are withdrawn. Thus, claims 1, 14, 17-22, and 33-36 are under examination.

New claims 35-36 have been added.

The amendment adds no new matter. The amendment is supported by the specification (see published application US 2007-0141184, page 3, paragraph [0084])

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

II. INDEFINITENESS REJECTION

The Office objected to the limitations "the form" and "which is solid or pasty at room temperature" in claims 1 and 17. Applicants have obviated this ground of rejection by amendment.

To obviate the rejection based on the limitation "the form", Applicants have amended claim 1 to recite "~~in the form of~~ a dosage form chosen between soft or hard capsules" and claim 17 has been amended to recite "~~in the form of~~ as capsicum resin".

To obviate the rejection based on the limitation "which is solid or pasty at room temperature", Applicants have amended claim 17 to recite "~~which~~ wherein said at least one lipophilic additive is solid or pasty at room temperature".

III. OBVIOUSNESS REJECTION

The claims stand rejected as obvious over of the combination of US 5,273,754 ("Mann"), US 4,393,049 ("Horrobin"), US 2002/0192308 ("Mamana"), and US 6,069,147

("Williams"). Applicants request withdrawal of the obviousness rejection for the reasons that follow.

Applicant's arguments do not attack the cited references individually. Instead, Applicant points out herein where the Office's assertions are inaccurate regarding the cited references and how the cited references are deficient in establishing a prima facie case of obviousness for the claims as presently amended.

"[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, 82 U.S.P.Q.2d 1385, 1391 (2007). Applicants submit that the Office has not met its burden to provide the required "articulated reasoning with some rational underpinning" for the reasons that follow.

A. Mann

1. Stomach Burning Sensation with Capsaicinoids

The Examiner asserts that "Mann teaches an appetite suppressant composition leading to a decrease in weight (col. 1, lines 5-10) comprising a heating carminative substance, such as standard oleoresin capsicum which contains capsaicin (thus capsaicinoids) (thus in the form of capsicum resin) (col. 2, lines 45-50). Mann also teaches that capsaicin is a preferred heating carminative substance, ...having a gastric heating effect exhibits a local anesthetic effect in the stomach (particularly upon the gastric nerves controlling hunger) when administered orally at a sufficient dose (col. 2, lines 30-40)." However, the Office completely obliterates the fact that capsaicinoids have a burning effect as it is disclosed in Mann (col. 3, line 30-35): "to diminish any undesirable burning sensation".

To overcome this problem, Mann proposes to add a "cooling carminative substance" which is absent in the present patent application. Said patent application uses a totally different approach to solve this burning sensation problem, which is the inclusion of capsaicin in an oil/lipophilic additive matrix. Nowhere in Mann, is it suggested or mentioned to use vegetable oils to solve this problem (see our precedent response).

2. Capsules

The Office also affirms that Mann further teaches that the appetite suppressant composition is in a form suitable for oral administration, and preferably as a capsule (thus solid or pasty at room temperature) (col. 4, lines 22-28). The Office apparently considers it inherent for capsules to be solid or pasty at room temperature. However, the properties of Mann's capsules cannot be "solid or pasty at room temperature".

Indeed, Mann discloses (column 4, lines 22-28) that "the appetite suppressant composition of the present invention is manufactured by combining all ingredients in a form suitable for oral administration, and preferably as a capsule or tablet".

Applicant notes that a tablet is compressed powder. Therefore, the term "capsule" back into context is unambiguous as a person of ordinary skill in the art would naturally understand that the capsules of Mann are capsules containing powder, as it is not specified any other active principle medium.

Moreover, in claim 1 of the present application, the Applicant respectfully submits that the term "solid or pasty at room temperature" only refers to the lipophilic additive, and not to the dosage form.

3. Conclusion of Mann

The only link between Mann's patent and the present application is the presence of capsaicin in the formulation and its inherent side effects. Therefore, and except for the presence of capsaicin, the present patent application is totally unrelated to Mann's patent.

B. Horrobin

The Office considers that Horrobin teaches that the treatment of obesity involves the administration of linoleic acid, generally in the form of vegetable oils such as sunflower oil and/or com oil (column 3, lines 30-35).

The Office omits to say, however, that this is a current technique for the treatment of obesity (column 3, line 31), which, in order to be effective requires the intake of other fats in the diet to be substantially reduced (column 3, line 34-36). Indeed, the presence of other fats

in the diet interferes with the conversion of linoleic acid to gamma-linolenic acid and thus reduces the effectiveness of the treatment (column 3, line 42-45).

Therefore, the skilled person in the art would not have used linoleic acid with at least one lipophilic additive as claimed in the present invention. This also proves that in the present case, it is not linoleic acid which is responsible for the treatment and prevention of obesity, and that linoleic acid's only contribution is on the solving of the side effects of capsaicinoids. It is not disclosed nor suggested in Horrobin such a property of linoleic acid.

Moreover, in view of Horrobin, the skilled person in the art would not have added capsaicin to linoleic acid if he had expected to cumulate the effects of these two compounds, but would have added gamma-linolenic acid, which is a poly-unsaturated fatty acid.

In view of Horrobin and Mann, a person of ordinary skill in the art would have not used capsaicinoids and linoleic acid, because this combination would have been nonobvious.

C. Mamana

The Office considers that Mamana teaches an appetite suppressant for controlling weight comprising green tea or green tea leaf extract (thus, one or more physiologically active components). The Office also asserts that Mamana teaches that the appetite suppressant is preferably administered orally in the form of capsule, etc. (thus, solid or pasty at room temperature).

First, Applicant notes that green tea is not the major ingredient of the present application and is not recited in the main claim 1.

Second, Applicant notes that the limitation "solid or pasty at room temperature" refers in claim 1 to the lipophilic additive, and not to the dosage form. Though capsules can contain a solid or paste, the wording of Mamana is unambiguous: "The composition is preferably administered orally in the form of a tablet, capsule, or powder". Thus, in Mamana the term "capsule" taken in context means a capsule filled with powder, and does not refer to solids or pastes.

Therefore, Mamana is inapposite in the present Office Action as containing subject matter (green tea) that is unrelated to independent claim 1 of the present Application.

D. Williams

The Office cites Williams for its disclosure of the use of polyethylene glycol (PEG) with thermogenesis stimulating drugs, to satisfy the limitation "lipophilic additive". The relevant passage in Williams, however, presents a more limited disclosure regarding PEG. Williams refers specifically to the lipophilic additives as "suspending aids" (column 3, lines 4-9). In particular, Williams mentions these "suspending aids" as being for "liquid preparations such as solutions, suspensions or emulsions", indicating that the suspending aids are for suspensions or emulsions.

Therefore a skilled person in the art would not consider the Williams' disclosure relevant to a preparation that did not require a suspending aid. It appears that the claim 1 does not refer to suspensions or emulsions. Thus it would appear to a person of ordinary skill in the art that no suspending aid, such as the PEG disclosed in Williams, would be needed.

Moreover, PEG is used in Williams as an excipient with moxonidine, which is a structurally different compound than capsaicinoids. PEG is used to help the suspension of the drug and absolutely not to decrease the burning effect of capsaicinoids in the stomach, as it is in the presently claimed invention.

Therefore, in view of Williams, the use of PEG with capsaicinoids, or even with another thermogenesis inducing compound different to moxonidine is totally unobvious.

E. Conclusion

In sum, Applicant considers the invention as claimed nonobvious for the reasons summarized below:

- Mann teaches that capsaicin may be useful for obesity treatment but acknowledges a tolerance problem due to the burning sensation in the stomach. To solve this problem, a "cooling carminative substance" such as menthol or herbal extracts are added. Such "cooling carminative substance" is absent from the composition of the present patent application.
- Horrobin teaches that gamma-linolenic acid, which is a more tolerant form (than linoleic acid when used with fats and oils), may be useful for treating obesity. Gamma-linolenic acid poly-unsaturated fatty acid is not recited in the

composition claims of the present application. Therefore the use of linoleic acid, and thus sunflower oil and/or corn oil, is unobvious in the present invention, which uses other lipophilic additives (such as beeswax).

- Mamana teaches that green tea leaves or extracts may be useful in the treatment of obesity. However, green tea leaves or extracts can be used as additional active principles which are not the subject matter of the main independent claim 1.
- Williams teaches that PEG may be used as a suspending aid for liquid formulations containing moxonidine. Williams does not teach that PEG may be used to diminish the burning sensation induced by capsaicinoids or other thermogenesis inducing compounds.

Nothing in the prior art cited would suggest the idea that the tolerance problem (burning sensation in the stomach) of using capsaicin could be solved by using an oil-based formulation containing common vegetable oil with a lipophilic additive. From the teaching of the references, it is therefore apparent that one of the ordinary skills in the art would not have had reasonable expectation of success in producing the claimed invention. Thus the invention as a whole is not prima facie obvious over the references.

Thus the rejection based on the "well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman," is unfounded in the present case. Also unfounded is the rejection based on alleged discovery of optimum or workable ranges involving only routine skill in the art when general conditions of a claim is disclosed in the prior art.

F. Data Showing Unexpected Results Are Commensurate In Scope

Concerning the Office's assertion that the data showing unexpected results (specification, page 11) is not commensurate in scope with the claims (Office Action, page 8), Applicant respectfully disagrees.

There is a technical basis for expecting that the other lipophilic additives (polyethylene glycol, candelilla wax, carnauba wax, polyethylene oxide wax, and petroleum wax) would behave similarly in the present invention. The minimal criterion to obtain the

expected result is that the quantities of these lipophilic additives are sufficient so that the encapsulated composition is either solid or pasty at room temperature and that this mass can melt at the human body temperature, i.e. 37°C. This criterion is essential to delay the release of capsaicin.

The choice and proportions of lipophilic additive(s) are numerous, so long as this physical property is reached. The techniques to obtain such lipophilic additives as disclosed in the claim 1, are well know by the skilled person in the art and can be determined by routine experimentation.

Consequently, the data is commensurate in scope with the full breadth of lipophilic additives as presently claimed.

Evidence pertaining to secondary considerations must be taken into account whenever present. M.P.E.P. § 2145, citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007). Accordingly the data in the present specification showing unexpected results, and the above explanation of how the data is commensurate in scope with the claims, would rebut any prima facie case of obviousness that may be made out.

The above arguments are directed to the independent claim 1. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. M.P.E.P. § 2143.03, quoting *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). By establishing nonobviousness of claim 1, Applicants also establish the nonobviousness of the dependent claims.

For all the reasons provided above, the obviousness objection should be withdrawn.

CONCLUSION

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a a credit card payment form being unsigned, providing incorrect information resulting in a

rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 31-AUG-2009 By _____

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

Rouget F. Henschel
Attorney for Applicants
Registration No. 39,221